Health Information Technology Policy Committee
Final
Summary of the March 17, 2010, Meeting

KEY TOPICS

1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC), welcomed Health Information Technology Policy Committee (HITPC) members and reminded the group that this was a Federal Advisory Committee Meeting and thus was being conducted in public.

2. Opening Remarks

David Blumenthal, National Coordinator for Health Information Technology, also welcomed the group and noted that the agenda items reflect the work and recommendations of the individuals and the workgroups; these efforts continue to be a large part of the foundation guiding the direction of the ONC and federal HIT policy.

3. Review of the Agenda

HITPC Co-Chair Paul Tang reviewed the day's agenda and then asked for and received approval of the minutes from the last meeting.

> **Action Item #1:** The Committee approved the minutes from the last meeting by consensus.

4. Strategic Plan Workgroup Update

Jodi Daniel, ONC, presented a "big picture" focus on the Strategic Plan Workgroup's framework. The HIT strategic vision and themes involve a learning health system that is patient-centered and uses information to continuously improve health and the health care of individuals in the population, identifying inherent values, the role of HIT, and the role of the federal government. Four themes have been identified: (1) meaningful use of HIT (inclusive of the statutory concept of meaningful use), (2) policy and technical infrastructure, (3) privacy and security, and (4) the learning health care system.

Paul Tang led the discussion regarding these themes. In a health system, there are a set of activities that are all conducted on behalf of and for the patients and the population—this generates a set of results that benefits society. The activities that benefit the population include engaging the consumers, providing care when needed, measuring the quality, and using that information to continuously improve and innovate and conduct research to improve this science. As a result of the activities for the benefit of population, there is a set of data that is collected, that when coupled to shared knowledge, can be used to improve care and outcomes as well as enhance value.

The view of ONC's support in creating the learning health system is implemented through the various provisions of the Health Information Technology for Economic and Clinical Health Act (HITECH). It includes meaningful use of certified electronic health records (EHRs) and is supported by activities such as the regional extension centers, workforce training grants, the exchange of health information through HIE grants and the Nationwide Health Information Network NHIN), and the standards, all of which need to have an infrastructure of research that continuously supports the creation and maintenance of the learning health systems.

Next steps will include an April 6 listening session during which a high-level summary of the recommendations for the strategic plan updates will be presented and public feedback will be solicited. The document will be finalized for presentation to ONC by May. The strategic framework will be finalized for presentation to the HITPC by May as well (this strategic plan will be drafted by ONC with HITPC input).

The following points were raised during discussion:

- One Committee member suggested explicit consideration of activity related to education, particularly as it relates to the synergy among the consumers, patients, and providers, as well as society.

- Committee members encouraged ONC to incorporate future-minded technology transitions in the strategic plan.

- Jodi Daniel discussed the strategies in Themes 2 and 4, explaining that they are strategies that focus on emerging technologies and adapting technical infrastructure and policy infrastructure in light of emerging technologies.

- Gayle Harrell commented on the need to be specific regarding the cost-benefit relationship and identifying the decision makers that evaluate these relationships. She added that the decision ultimately rests with the patient, and that the patient has an integral role to play in determining the ultimate value of HIT to him or her. One Committee member suggested that the decision ultimately needs to reside with the patient. Adam Clark agreed, adding that in the enhanced value section of the strategic plan, it should be noted that the purpose is to inform patients—bringing knowledge to them to help them make informed decisions. Paul Tang agreed that these comments should be included as bullet points in this part of the strategic plan.

- In response to a question regarding the timeframe for the strategic plan, Jodi Daniel explained that it will focus on a 5-year period.

- Jodi Daniel encouraged HITPC members to participate in the upcoming listening session and hear what is said by the public.

Action Item #2: Bullet points will be added to the strategic plan reflecting: (1) the comments from Gayle Harrelll regarding cost-benefit relationships and the role of the patient as well as (2) comments from Adam Clark emphasizing the informed patient.

5. Certification/Adoption Workgroup Report on HIT Safety Hearing

Marc Probst explained that at the Safety Hearing, HIT-related issues were discussed, with the majority of the topics coming from local perspectives and conditions as well as the configuration of these systems. Surprisingly, most issues were not with the code supplied by the vendor. Having the ability to quickly disseminate information around problems is key to the ability to react to HIT issues that could result in safety problems—this should be a main focus. Every organization is unique. Because of that, there is a local responsibility to HIT safety that the vendors are not going to be able to keep up with. Local capabilities are needed as part of the infrastructure moving forward, including the tools, processes, and organizational structures that allow for the communication of this information. One of the biggest points heard during this HIT safety discussion is that if it is done too quickly, without the right processes, procedures, etc. in place, a number of safety issues could be introduced.

Paul Egerman discussed the information shared and learned during the Workgroup calls. In summarizing the HIT Safety Hearing, he described anecdotes and experiences backed up with very little data, pointing to a 2007 study by Dr. Joan Ash, which focused on computerized physician order entry (CPOE) as well as data from the U.S. Food and Drug Administration (FDA). There is complete confidence in HIT and in the effectiveness of HIT systems. Not one presenter at the hearing indicated that the systems are dangerous. However, there are many areas of concern that need to be addressed to ensure that this is done correctly and that the full potential of these systems is realized. One concern is the frustration level of the physicians, clinicians, and nurses that their specific issues are not being addressed.

The problems were broken down into four groups: (1) technology issues, (2) the complex interactions of people and technology, (3) training and implementation, and (4) interoperability. The Workgroup has developed preliminary recommendations. One is to establish a patient-centered approach to safety, which is consistent with the National Coordinator's vision of a learning health and health care system. The focus would be on hazards and "near misses." Another preliminary recommendation is to initiate a national transparent information system. Furthermore, the Workgroup suggests that a culture of improvement needs to be created by each health care entity. In support of this goal, there are a number of recommendations in the areas of patient engagement, training and implementation, establishing a national database, a clinician feedback button, certification to include vendor custom alerts, and best practices. Paul Egerman presented a series of open questions to HITPC members, such as: Should we recommend a special HIT Patient Safety Oversight function or an NTSB-like entity that investigates serious patient safety concerns? And should whistleblower protection be expanded/changed as part of this process?

The next steps for the Workgroup are to solicit feedback from presenters at the hearing, solicit feedback from the HITPC and the public, participate in conference calls on March 25 and March 29, and prepare a final presentation on April 21, 2010.

The following was noted in discussion:

- In response to a question, Paul Egerman explained that there is little reliable information on the proportion of importance of errors that are associated with the technology as opposed to all of the other components included in the technology environment. More evaluation in this area is needed.

- Paul Egerman explained that the certification process does include a surveillance capability, and that this surveillance capability is very important. The goal is to ensure that these systems work in the field the way they are tested to work, and that they have feedback into the certification process.

- With regard to liability issues, Paul Egerman noted that the Workgroup tried to address these in a number of ways (e.g., by focusing more on hazards and near-misses, ensuring that there is a capability for reporting issues confidentially).

- The issue of competency testing was discussed at length. Systems are installed, but there is nothing done to test the competency of the user. Sometimes, the systems are designed effectively and work very well, but the people using them are not appropriately trained. The competency of the vendors installing the systems and teaching people safely how to use them from the start need to be considered as well.

- In response to a question about the several lines for reporting problems and making them available to the consumer, Paul Egerman indicated that the Agency for Healthcare Quality and Research, along with other patient safety organizations, have done a significant amount of work in this area.

- A discussion ensued regarding the special considerations that may be necessary for small groups, rural hospitals, and safety nets. It was noted that there have not been reports of problems at small physician groups or at rural hospitals. Most anecdotes tended to be at large complex organizations and most activity in these cases was on the inpatient side

- The question was posed as to the role of certification generally in improving the safety of information technology? Paul Egerman responded to a question about the role of certification in improving the safety of HIT by explaining that it is hoped, in collaboration with the FDA, to design a process to make sure that the products are designed well and the vendors have in place the right mechanisms to evaluate potential hazards and keep track of the results.

6. NHIN Workgroup Report

David Lansky explained that there are three topics on the agenda for the Workgroup: (1) continuing consultation with the National Institute of Standards and Technology (NIST) and others about the assurance framework for identity-proofing and transmitting authentication credentials across the network, (2) the trust framework, and (3) HIE between state and federal activities.

With regard to the assurance levels issue, in February the Workgroup began a consultation with NIST to help understand how other disciplines and sectors of the government enterprise have addressed identity assurance. There were no quick answers from existing history that could simply be adopted in the existing infrastructure and turn it on to our process. The Workgroup will continue to work with NIST and others to look at the right tools that will make sense to support ONC's charter.

The NHIN Direct program will be underway in the next several months to produce tools; the Workgroup will consult with experts and help coordinate what is done at ONC and the policy level with what the states requirements are.

With regard to the trust framework, there are five high-level topics that are under discussion: (1) code of conduct, (2) oversight and transparency, (3) accountability and enforcement, (4) confidence in exchange partner identities, and (5) technical requirements for information exchange.

In response to a question regarding the interaction between this trust framework and the Privacy and Security Workgroup discussions, David Lansky noted that there have been side conversations with Privacy and Security Workgroup members, as well as those from the NHIN and HIE Workgroups. It is recognized that there is a great deal of overlap and that a coordinated effort is needed to understand how each group and contribute to a solid recommendation in this area.

7. Report on Certification NPRM

Steven Posnack and Carol Bean provided this report to HITPC members and described the policy architecture required to implement meaningful use. The first regulation in this area relates to the meaningful use regulations that specify objectives and measures—the behaviors that eligible professionals and eligible hospitals will need to meet in order to get their incentive payments. That regulation is correlated with the Interim Final Rule (IFR) on standards and certification criteria, released and published on January 13, which specifies certification criteria and the underlying standards in those certification criteria that complete EHRs and EHR modules would need to include to support a meaningful user's attempt to achieve meaningful use. The third and final interdependent regulation that was just published relates to the certification program and how these complete EHRs and EHR modules get certified to provide assurances to eligible professionals and eligible hospitals that adopt them so they are going to have the technology capabilities they need to become meaningful users.

Two new acronyms were introduced, for the ONC Authorized Testing and Certification Body (ONC ATCB) and ONC Authorized Certification Body (ONC ACB). Using the certification criteria and standards, either of these two bodies will test and certify complete EHRs and EHR modules.

With regard to HITPC recommendations made to ONC, the HITPC recommended that ONC focus on certification on meaningful use; the Office has been moving in that direction. HITPC also recommended leveraging the certification process to improve progress on privacy and security interoperability, a foremost recommendation that ONC has embodied in all of its regulatory processes. To develop a short-term certification transition plan, ONC has proposed both a temporary certification program and a permanent certification program. There are two purposes for the Notice of Proposed Rule Making: (1) establish the process for the National Coordinator to "authorize" organizations to perform HIT testing and certification, and (2) specify how complete EHRs and EHR modules would be tested and certified.

In the rule-making approach, there are two proposed programs, the temporary certification program and the permanent certification program. Both programs have a comment period and include an open application process. Organizations would be authorized to perform the certification of complete EHRs, EHR modules, or both. There are accreditation requirements proposed for the permanent certification program, in which the authorization focus is solely on certification. Regarding accreditation, in the permanent certification program, the National Coordinator would approve an accreditor for the certification competencies; ONC proposes that it would work with NIST through the National Voluntary Laboratory Accreditation Program and that they would accredit the testing laboratories for complete EHRs and EHR modules. ONC has specified particular authorized methods that these bodies would perform for testing and certification. The primary method required is that they be able to test and certify complete EHRs at their facility.

A high-level view of the temporary certification program, is that it is essentially one body authorized by the ONC to do both testing and certification. NIST has been consulting with ONC and has helped to design the evaluation criteria for the testing and certification bodies. NIST also is developing the test method for the technical requirements. The test methods are being published publicly on NIST's Web site.

A high-level view of the permanent certification program is that it is the formal accreditation process for both testing and certification and that there is a formal separation between testing and certification. A single organization could do both testing and certification, but there are many requirements for the separation of those processes.

ONC anticipates that there will be multiple certification bodies and proposed in the NPRM that it maintain a master certified HIT products list that would be the aggregate of all of the products and technologies that have been certified. That certified public list would be available to the public on the ONC Web site with the intention of addressing the needs of purchasers or holders of the certified technology program.

The following points were raised in discussion:

- A question was posed regarding permanent certification if there was a plan to place a limit on a number of bodies that might be certifying? Carol Bean noted that there is no plan to place a limit on the number of bodies that could carry out permanent certification. However, it is expected that there is a natural limit on the number of organizations that are qualified to do this.
- One HITPC member expressed concern about having multiple entities doing the certification and that whichever group does so at the lowest price would be the front runner. It was noted that the requirements will be the same regardless of who does the testing and certification.

- A discussion ensued regarding how fast-moving changes in the technology and the associated standards will be accommodated. The Workgroup is going to review the public comments received on the IFR to try to determine a way to both balance certification with a snapshot of a complete EHR and EHR module capabilities at the current point in time versus where the industry is going if new standards, code sets, etc. are released.

8. HIT Standards Committee Update

John Halamka, Vice Chair of the HIT Standards Committee (HITSC), reminded HITPC members that the HITSC includes four Workgroups, in the areas of Clinical Operations (led by Jamie Ferguson), Clinical Quality (led by Janet Corrigan), Privacy and Security (led by Dixie Baker), and Implementation (led by Aneesh Chopra).

Clinical Quality Workgroup

Janet Corrigan explained that efforts are currently underway to retool approximately 110 measures, all of the measures identified in the NPRM. The National Quality Forum (NQF) is working actively with the various measure stewards on the retooling efforts and expects that the measures will have eSpecifications. This work should be completed by September. One issue that has not been addressed is that currently there is no test deck or test bed in place to run eSpecifications for the various measures to see whether or not they accomplish what they are intended to accomplish. Another issue is that as a result of the initial retooling effort, value sets will begin to be identified. It will be important to build these value sets that will then support the specification of all of the many quality measures. Out of the initial retooling effort, starter value sets will be identified, but this is an issue that will need to be addressed on a broader scale going forward by the HITPC and HITSC.

The Clinical Quality Workgroup is also awaiting more direction from the HITPC as to the types of measures that will be focused on for 2013 and 2015. For the 2011 meaningful use measures, the Workgroup took care of the existing performance measures that are well specified and have been evaluated and vetted. If the HITPC's desire is to move aggressively in 2013 toward aspects of performance, work will need to begin immediately because the pipeline and timeline for measure development and testing is at least 8 months to 2 years.

Floyd Eisenberg explained that in the IFR in terms of identifying allergies, there is discussion about using UNII codes. There are two issues for managing quality measurement: (1) allergies must be known, so this needs to be accomplished sooner for measurement (there also is value in

having the component level allergy identified); and (2) vital signs—there is no identified terminology in the 2011 time frame and they are needed for some of the near-term quality measures, specifically blood pressure and body mass index (BMI). Having a single vocabulary would be beneficial from the quality perspective, and the Workgroup is suggesting LOINC. With regard to CCR versus CD, the Workgroup agreed that there is benefit for interoperability sharing summaries. Most of the quality data work is based on very discrete data level definitions identified within the CDA architecture, of which CCD is one example, so CCD was felt to be more beneficial.

In terms of reporting out, there was no disagreement with the PQRI XML, except that the use of it primarily is in the ambulatory community for reporting. The Workgroup agrees that QRDA is not ready at this point for quality reporting, but a CDA-based model appears to make sense.

Clinical Operations Workgroup

Jamie Ferguson reminded HITPC members that the Clinical Operations Workgroup has the responsibility for making standards recommendations and certification criteria for the content exchange standards and vocabulary standards that are used. The Workgroup's Vocabulary Taskforce has started to hold a series of hearings on the needs for controlled vocabularies for meaningful use. The first hearing was held last month and the second hearing will be next week. Key participants in the first hearing included panels of EHR vendors, vocabulary service providers, and the messaging standards organizations. Some of the messages were that there is a need for a centralized process and a centralized repository for the value sets. There is also a need for starter sets, perhaps frequency-based subsets of the required vocabulary standards to give EHR implementers a starting point. There was a strong agreement on the need for using the private sector.

With regard to the IFR, the primary theme is that there is a need to balance and enable conflicting requirements for both flexibility and specificity in the content exchange and vocabulary standards. Flexibility is needed for both innovation and advancement to occur, but specificity at a detailed level is required to achieve interoperability between any two eligible professional offices or hospitals. The Workgroup has recommended an alternative mechanism than that in the IFR to meet these different requirements simultaneously, moving to a higher level or a less specific level of the adopted standards for content exchange. The Workgroup recommends that a clinical document architecture of HL7 in addition to the CCR would be the standard for patient summaries, NCPDP script for medication transactions, the standard HIPAA transactions, the X12 4010A1 and X12 5010 for the administrative transactions. For quality reporting, the Workgroup recommends that both XML and the clinical document architecture should be adopted, so the SML Web protocol standard would then be used.

The Workgroup also recommends implementation guide floors to remove all optionality from the base standards. The group also added recommendations about the need for vocabulary starter sets and that there should be an adopted vocabulary (with the recommendation that both SNOMED CT and LOINC be adopted for that purpose). In addition, the Workgroup has requested clarification on the scope of interoperability in terms of where these standards should

apply to the interoperability of content exchange outside the boundaries of closed systems (i.e., between entities).

Privacy and Security Workgroup
Dixie Baker noted that a number of topics addressed in the area of privacy and security such as authentication, access control, and auditing help protect not only patient privacy, but also address the important area of quality of care and patient safety. Although the overall emphasis is on information exchange, in the security area internal trust mechanisms that exchanges depend on are critical areas of focus. There is a need to look within the organization, not just at the intersection between organizations. The Workgroup is specifying or recommending technology standards and certification criteria to support privacy and security policy as well and safety and quality.

The Workgroup has provided a number of comments on the IFR. It agrees that the certification program should include EHR modules, but this presents challenges with respect to enterprise-wide privacy and security. The Workgroup recommends that whenever an EHR module is submitted for certification that it address all of the security certification criteria in the same way as the HIPAA security rule discusses making implementation specifications addressable. A body of certifiers such as that described earlier in the meeting is in the in the best position to maintain a list of standards that are acceptable for meeting a particular functional standard in the IFR—the Workgroup recommends that the certification program incorporate maintaining a list of acceptable standards.

The American Recovery and Reinvestment Act (ARRA) requires that covered entities provide electronic access for consumers, but the IFR does not use the "electronic access;" rather, it uses the term "online access." The Workgroup is concerned that this term is not well defined. The Workgroup also is concerned that consumers want to have a copy of their record and feels that the language around this issue needs to be clarified.

In terms of encryption, the Workgroup feels that the IFR should specify the advanced encryption algorithm (AES) in the case of symmetrical encryption (using the same key to both encrypt and decrypt). This is NIST's recommendation as well.

The Workgroup also recommends that with regard to the NHIN trust framework, both certification criterion and a standard should be added in several places for requiring the authentication of both ends of the trusted link before that trusted link is established.

In the area of accounting for disclosure, the Workgroup has noted an inconsistency in the timeline. ARRA indicates that the requirement for accounting for disclosures will go into effect in 2011, but the meaningful use measure specifies 2015. This issue needs clarification. Currently, health care operations and organizations are not required to account for disclosures of treatment, payment, and health care operations. Moving from this environment will require significant changes in workflows within organizations. The Workgroup recommends that the HITPC and HITSC coordinate a recommendation to the ONC on this matter.

Implementation Workgroup

The Implementation Workgroup has been focusing on what could be created as a toolkit or starter kit that could be handed off to the regional extension centers or to any group that is implementing an EHR or HIE to accelerate their efforts. Federal Chief Technology Officer Aneesh Chopra has been chairing hearings to gain input from implementers, policy makers, and others to gather information on such a starter kit.

The Implementation Workgroup has created a set of guiding principles, such as: (1) keep it simple; (2) think big, but start small; (3) building incrementally in phases is likely to lead to adoption quicker; (4) keep the costs as low as possible; (5) do not try to create a one-size-fits-all standard; (6) separate content from transmission; (7) create publicly available vocabularies and code sets; and (8) make sure that the quality measures are EHR friendly.

Implementation Workgroup members emphasize the fact that the coordination between the HITSC and HITPC should be seamless. The disclosures timeline between the Committees needs to be addressed so that adoption of these valuable consumer tools can be balanced with the reality of implementation.

The following was noted in discussion:

- Concern was noted about there potentially not being enough support or a mechanism for standards refinement. After the standards are released, they are going to need to evolve.

- The HITSC will not only need to work on the selection of certification criteria and technical standards, but also on creating a new standards harmonization framework.

- Floyd Eisenberg responded to a question by stating that whereas an EHR might send patient-level data to an HIE or another aggregator of information which then would, as long as that were also certified for that process, be meaningful. The Department of Health and Human Services defines "meaningfulness." In the most complicated case, an EHR could send data to an HIE that routes these data to an aggregator which then hires a calculator to carry out risk adjustment and computation, and then there is a receiver, CMS for example, that would receive numerators and denominators. The EHR could be sending patient-identified detail data to an HIE in which the aggregator could deidentify or hash it. The Clinical Operations Workgroup is recommending standards and certification criteria that enable all of these functions regardless of where those modules are located in terms of different business arrangements.

- Jamie Ferguson clarified that the Clinical Operations Workgroup is recommending that HL7 v2 would be the adopted standard, and that would therefore include all sequential dot release addenda and subsidiary versions of v2 (including 2.5, 2.5.1, 2.6, etc.). These are all different parts of the v2 standard. The implementation guide is extremely specific such that it takes one of those particular addenda or subspecifications of the v2 standard and essentially removes optionality by constraining each individual data element.

- When asked what role the HITSC can play in helping move toward a vision of ongoing real-time online access to information for patients and their caregivers, Aneesh Chopra noted that

consumer access to information stands out as a major issue that needs to be addressed. The National Cancer Institute (NCI) publicly declared that it would provide consumer access, reference implementation, and support tools. NCI is working with a host of EHR vendors in the cancer community to provide information to the patient and to provide information for research purposes.

9. Remarks on the NPRM Comments Received and Processed

Tony Trenkle explained that all of the input submitted on the NPRM has to be addressed with a comment response. CMS tends to group with patterns, identify rationale and data, and look at this input in terms of statutory policy and operational. To date, 2,000 comments on the NPRM have been received; CMS has reviewed approximately one-half of them.

Comments have been submitted that ask for a lowering of the bar or for additional clarification on objectives and measures. The issue of meaningful use flexibility came up often in HITPC discussions, and there has been a nearly universal requirement to earn the incentive. There have been various suggestions about how that should be done (e.g., setting it as a percentage of measures that must be met, setting some measures as core and others as optional, scaling the amount of incentive payment to the level of completion of meaningful use, reducing the number of measures, reducing the number of clinical quality measures, reducing the thresholds of measures).

A second issue is the denominator, in which information cannot be captured through the EHR or where it becomes a manual process. A number of organizations have indicated that they do not feel they should be included in this. There also were concerns about CPOE, particularly from hospitals. Additionally, a number of organizations expressed concern about allowing states too much flexibility in terms of making changes to meaningful use criteria.

Approximately 80 percent of the comments have been focused on meaningful use of quality measures. With respect to the quality measures, the issues included avoiding redundant reporting, limiting the measures to those already on track to be EHR-ready, clarification of measures, and questions on whether there should be core measures.

The definition of "hospital-based eligible professional" has been a major topic, the definition of hospital identification, as has the issue of multi-campus hospitals and whether they should be separately identified and given payment.

CMS will categorize these comments and begin to tease out the high-policy issues, develop the comments and responses, and then try to work on a parallel path to get some of the policy issues discussed early on by HHS and the Office of Management and Budget, moving towards a final regulation.

Steve Posnack provided an update on the IFR with regard to standards and certification criteria. Several hundred comments have been received on the IFR, those that are relevant have been posted online. There were many comments about the specific standards; many policy decisions will need to be made. ONC will be working with CMS with respect to objectives and certification criteria; as policy decisions get made, ONC will try to reflect them in the

certification criteria and standards that it has adopted. He reminded HITPC members that the certification criteria and standards that have been adopted are for certifying the products and do not represent what organizations need to meet.

10. Clinical Laboratory Improvement Amendments (CLIA)

Jessica Kahn noted that on March 1, CMS issued its most recent CLIA guidance on the electronic exchange of laboratory data. This project has been ongoing for several years; within the past 6-7 months, it has been raised to senior leadership both at ONC and CMS as potentially a barrier to the exchange of laboratory data. A public hearing was held on this topic—some of the recommendations aired at the hearing also relate to EHR standards and certification. A CLIA memo also was drafted that included many of the comments discussed at the hearing, such as an emphasis on explicitly clarifying the role of HIT within the existing CLIA regulations. CMS explicitly defined what the role of HIT would be and clarified the issue of patient's access to results.

Jessica Kahn explained that the transmission of laboratory data through a health information organization is permitted. If it is on the laboratory requisition, then an agent of the authorized person, be it EHR vendor or an HIE, can receive the lab results directly on behalf of the authorized person. A laboratory can contract with another entity to facilitate the delivery of those patient records.

One of the primary concerns that had been raised to ONC and CMS leadership was the burden for verification that the results were transmitted in an accurate and timely way when transmitted electronically. CMS clarified that CLIA does not require visual inspection of each EHR installation—CLIA does not specify how often or how one verifies the accurate transmission of lab results, only that it is done. CMS included in the CLIA memo in several places an important statement, that it anticipates that lab adoption and use of departmentally recognized standards such as HL7 2.5.1 and LOINC and the NHIN specifications would reduce the laboratories' frequency for verification of the accuracy of the transmission of results.

The area of patients' access to lab results required some clarification. CMS has clarified in its interpretive guidelines in what scenarios under CLIA a patient can receive their test results directly. This relates to whether they are an authorized person or whether they can be considered an individual responsible for using the test results; CMS clarifies where state laws might have some interplay there.

For much of the CLIA staff and regional CMS office staff, these issues are new. This guidance is used by surveyors to determine whether laboratories are compliant. CMS' immediate short-term goal is to ensure that the surveyors understand and are applying the new CLIA guidance correctly. At the same time, there are some larger policy issues that need to be examined. In particular, patients' access to their lab results within the confines of HIPAA and CLIA has been identified as a shared policy goal—CMS, ONC, and the Office of Civil Rights will collaborate on this issue. As these policies evolve and there is more maturity in the standards and practices in the exchange of laboratory information, CMS will revisit its CLIA interpretive guidelines.

11. Public Comment

One member of the public emphasized that the patient is the ultimate recipient of meaningful use and commended ONC for promoting its efforts in regard to EHR adoption. It was suggested that a blog, Web site, or other mechanism be used to provide the public with additional information and to obtain additional public input.
Another member of the public also lauded ONC for its efforts and suggested that NIST, with its role in the certification process, may be lacking the requisite EHR-related expertise.

SUMMARY OF ACTION ITEMS

Action Item #1: The Committee approved the minutes from the last meeting by consensus.

Action Item #2: Bullet points will be added to the strategic plan reflecting: (1) the comments from Gayle Harrelll regarding cost-benefit relationships and the role of the patient as well as (2) comments from Adam Clark emphasizing the informed patient.